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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,970	01/13/2004	Kevin T. Foley	MSDI-223/PC444.06	3770
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KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER HOFFMAN, MARY C	
			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	DELIVERY MODE
			11/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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**Office Action Summary**

Application No.

10/756,970

Applicant(s)

FOLEY ET AL.

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 54-79 is/are pending in the application.
- 4a) Of the above claim(s) 71-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-70 and 74-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 08/24/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54-70 and 74-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (U.S. Patent No. 5,454,365).

Bonutti discloses instrumentation comprising an elongate member (FIG. 2) extending along a longitudinal axis and including a deformable distal portion (ref. #60) having an initial configuration and an expanded configuration wherein the deformable distal portion is outwardly deformed to define at least one transverse projection, the at least one transverse projection arranged along a single transverse axis such that at least a portion of the spinal structure is uniaxially displaced along the transverse axis. Displacement of the at least a portion of the spinal structure is can be directionally controlled. Displacement of the at least a portion of the spinal structure is can be unidirectional. Outward deformation of the at least one transverse projection is selectively controlled to generate a controlled magnitude of force against a body structure, such as a spinal structure. The expanded configuration defines a pair of the transverse projections arranged generally opposite one another along the transverse axis. The elongate member comprises an inner actuator member (ref. #18) disposed

within an outer sleeve member (ref. #40), a distal portion of the sleeve member being outwardly deformed to define the at least one transverse projection in response to relative displacement between the actuator member and the sleeve member. The relative displacement between the actuator member and the sleeve member is relative linear displacement. The relative displacement between the actuator member and the sleeve member is regulated to generate a controlled magnitude of force. The instrumentation further comprises an actuator mechanism (ref. #22/16) coupled between the actuator member and the sleeve member and being operable to impart the relative displacement therebetween. The actuator mechanism comprises a first portion coupled to the actuator member; and a second portion coupled to the sleeve member and engaged with the first portion; wherein relative rotation between the first and second portions imparts relative linear displacement between the actuator member and the sleeve member to cause the distal portion of the sleeve member to reform from the initial configuration toward the expanded configuration. The deformable distal portion comprises at least one flexible strip of material, the flexible strip of material having an outwardly buckled configuration defining the at least one transverse projection. The deformable distal portion comprises a pair of the flexible strips of material disposed generally opposite one another, the pair of flexible strips of material defining a pair of transverse projections disposed generally opposite one another when transitioned to the outwardly buckled configuration. The flexible strip of material has a predetermined shape to provide controlled transitioning to the outwardly buckled configuration. The predetermined shape includes a series of arcuate portions. The deformable distal

portion defines a plurality of slots (ref. #68/62), the slots facilitating outward buckling of the deformable distal portion to define the at least one transverse projection. Each of the plurality of slots has a predetermined shape to provide controlled outward buckling. The predetermined shape is at least partially comprised of an hour-glass shape.

Bonutti discloses the claimed invention except for 1.) the transverse projections extending in a uni-axial direction aligned with the single transverse axis (i.e. Bonutti does not disclose that there are only two oppositely, equally spaced projections; rather, Bonutti discloses a plurality of projections equally or unequally spaced apart) and 2.) the deformable distal portion being at least partially formed of a shape-memory material.

1.) While Bonutti does not explicitly teach two oppositely spaced transverse projections, Bonutti does disclose that the number of projections may vary and that they may be spaced equally (col. 5, lines 1-4) in order to provide varying expansion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the Bonutti device with two, oppositely spaced projections in view of Bonutti's own disclosure in col. 5, lines 1-4 to provide varying expansion. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to construct the Bonutti device with two, oppositely spaced projections, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

2.) It would have further been obvious to one having ordinary skill in the art at the time the invention was made to make the deformable distal portion of Bonutti at least partially formed of a shape-memory material, since it has been held to be within

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the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 54-58, 64-70 and 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva et al. (U.S. Patent No. 5,885,258).

Sachdeva et al. instrumentation comprising an elongate member (FIG. 3) extending along a longitudinal axis and including a deformable distal portion (ref. #32) having an initial configuration and an expanded configuration wherein the deformable distal portion is outwardly deformed to define at least one transverse projection, the at least one transverse projection arranged along a single transverse axis such that at least a portion of the spinal structure can be uniaxially displaced along the transverse axis. Displacement of the at least a portion of the spinal structure is directionally controlled. Displacement of the at least a portion of the spinal structure is unidirectional. Outward deformation of the at least one transverse projection is selectively controlled to generate a controlled magnitude of force against the at least a portion of the spinal structure. The expanded configuration defines a pair of the transverse projections arranged generally opposite one another along the transverse axis. The deformable distal portion comprises at least one flexible strip of material, the flexible strip of material having an outwardly buckled configuration defining the at least one transverse projection. The deformable distal portion comprises a pair of the flexible strips of material disposed generally opposite one another, the pair of flexible strips of material defining a pair of transverse projections disposed generally opposite one another when

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transitioned to the outwardly buckled configuration. The flexible strip of material has a predetermined shape to provide controlled transitioning to the outwardly buckled configuration. The predetermined shape includes a series of arcuate portions. The deformable distal portion defines a plurality of slots, the slots facilitating outward buckling of the deformable distal portion to define the at least one transverse projection. Each of the plurality of slots has a predetermined shape to provide controlled outward buckling. The predetermined shape is at least partially comprised of an hour-glass shape. The deformable distal portion is at least partially formed of a shape-memory material, the deformable distal portion being reformed from the initial configuration toward the expanded configuration in response to the imposition of stress and automatically reformed back toward the initial configuration upon removal of the stress.

Sachdeva et al. disclose the claimed invention except for the transverse projections extending in a uni-axial direction aligned with the single transverse axis (i.e. Bonutti does not disclose that there are only two oppositely, equally spaced projections; rather, Bonutti discloses a plurality of projections equally or unequally spaced apart) and

While Sachdeva et al. do not explicitly teach two oppositely spaced transverse projections, Sachdeva et al. do disclose that the amount of slots, and consequently projections, may vary (col. 2, lines 42-45) depending on the intended function of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the Sachdeva et al. device with two, oppositely spaced projections in view of Sachdeva et al.'s own disclosure in col. 2, lines 42-45 depending on the intended function. It would have further been obvious to one having ordinary skill

in the art at the time the invention was made to construct the Sachdeva et al. device with two, oppositely spaced projections, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Response to Arguments***

Applicant's arguments filed 08/13/2007 have been fully considered but they are not persuasive.

Applicant argues that the claim amendments render the application claims patentable over the prior art. The examiner respectfully disagrees with Applicant's assertion that the claims are not subject to a 35 U.S.C. 103(a) obviousness rejection over Bonutti and Sachdeva et al. It is noted that Applicant has not provided any explanation or other evidence as to why the claims would not be subject to rejections under 35 U.S.C. 103(a) obviousness rejections over the Bonutti or Sachdeva et al. references. Applicant's arguments on page 11, first paragraph, and page 12, second paragraph, state that one of ordinary skill in the art would not be motivated to modify either the Bonutti and Sachdeva et al. references to meet the current claim language amounts to a general allegation because it does not specifically point out why these references could not be modified to meet the amended claim language. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.



Absent an explanation or showing otherwise by Applicant, it is the examiner's opinion that these references, Bonutti and Sachdeva et al., can be properly modified to meet the current claim language.

The rejections are deemed proper.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

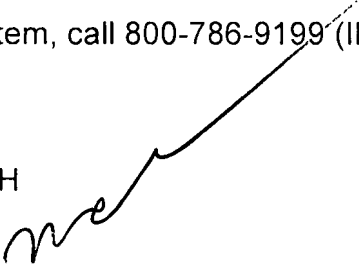

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH

A handwritten signature in black ink, appearing to be 'me' or similar, written diagonally across the page.A handwritten signature in black ink, appearing to be 'E. Robert', written diagonally across the typed name.

EDUARDO C. ROBERT  
SUPERVISOR, PATENT EXAMINER